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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,939	11/07/2001	Harold G. Craighead	1153.009US1	5674
21186	7590	03/08/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,939

Applicant(s)

CRAIGHEAD ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/26/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 35-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I comprising claims 1 – 25 and 35 – 50 in the reply filed on 4/19/2004 is acknowledged. Claims 26 – 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This application contains claims 26 – 34 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

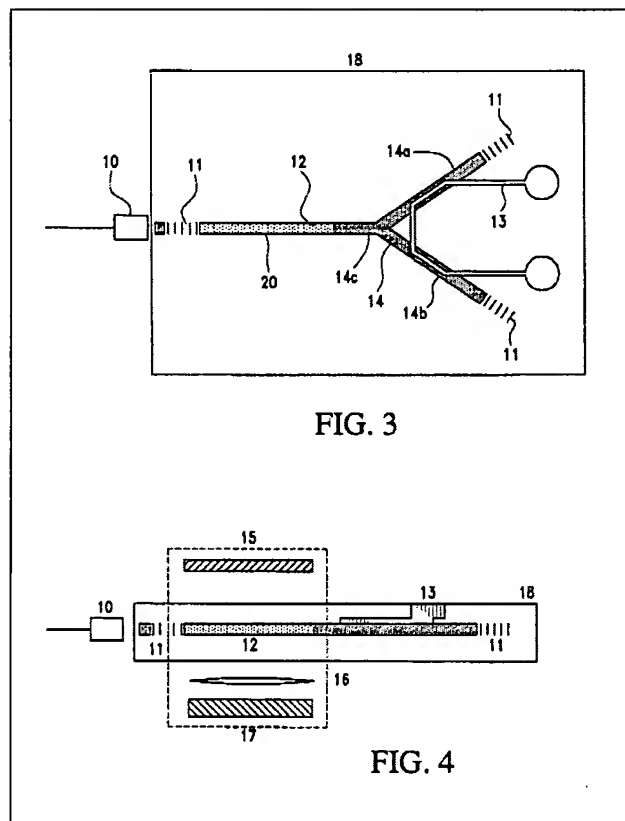
Claims 1 – 11, 13 – 25, 35 – 43 and 45 – 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Lading et al. (U.S. Pat. No. 6,493,090 B1). Regarding claims 1 – 6, Lading et al. teach an apparatus comprising a duct (e.g., microfluidics handling system 13), wherein the

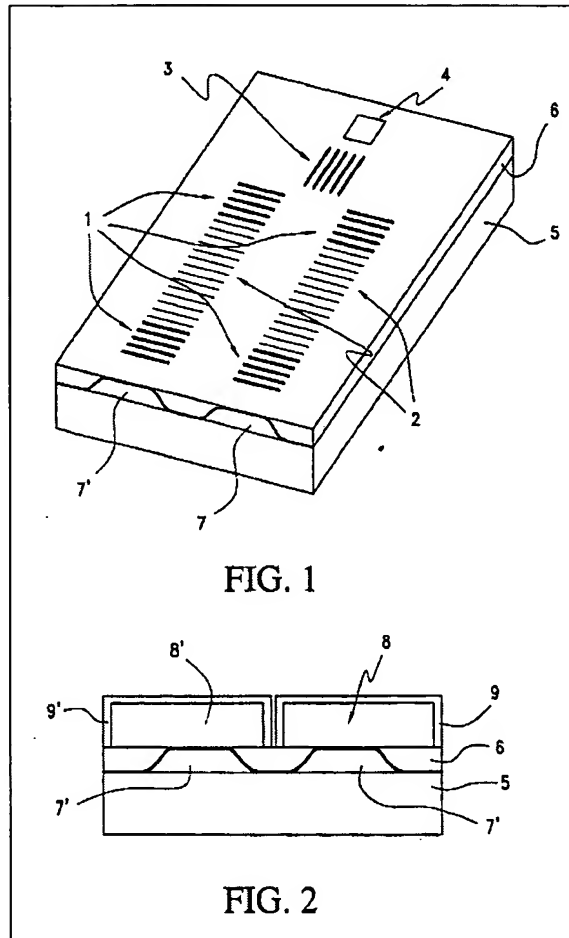
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duct has a first wall and a substantially parallel gap formed by a first transparent wall and a second transparent wall (see col. 4, line 15 – col. 14, line 57; figures 1 – 6). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). Regarding claims 7 – 11, Lading et al. anticipate the incorporation of an immobilized binding partner for facilitating analyte detection (see col. 1, lines 1 – 61; col. 4, lines 53 – 59; col. 5, lines 54 – 65; col. 6, lines 41 – 54). Regarding claims 13 – 17 and 20 – 25, 42, 43, and 45 – 50, Lading et al. further anticipate an apparatus comprising: a first translucent plate (e.g., the top of outer walls 9 or 9’); a plurality of sidewalls (e.g., the sidewalls of 9 or 9’); a second translucent plate (substrate 5); a light means or source (e.g., lasers 60 & 62); and a light receiver or sensor means (detector 10 or optical spectrum analyzer 82) (see col. 12, lines 23 – 25; figures 1 – 6). Lading et al. do teach a chamber means for containing a sample fluid, which also contains immobilized binding partners, such as antibodies or antigens (see col. 1, lines 1 – 67 & col. 5, lines 1 – 65). Lading et al. teach the use of a various types of light detectors, such as photodiodes or photomultiplier tubes for detection (see col. 7, lines 8 – 19). Lading et al. further teach the incorporation of a signal processing means, such as a computer (see col. 8, lines 7 – 10). Lading et al. teach the use of various types of lasers, such as gas lasers, argon lasers, solid state lasers, etc., which are well known in the art (see col. 4, lines 60 – 67). Regarding claims 18 and 19, Lading et al. teach the

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incorporation of prisms as optical elements (see col. 7, lines 26 – 35). Regarding claims 35 – 41, as discussed above, Lading et al. teach all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). In addition, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01).





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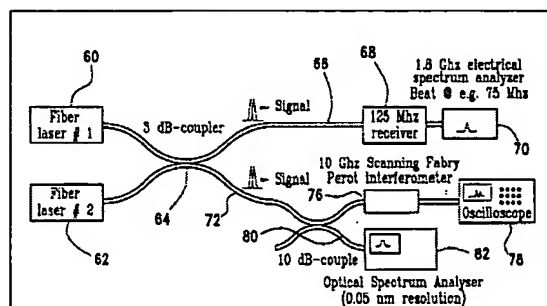


FIG. 5

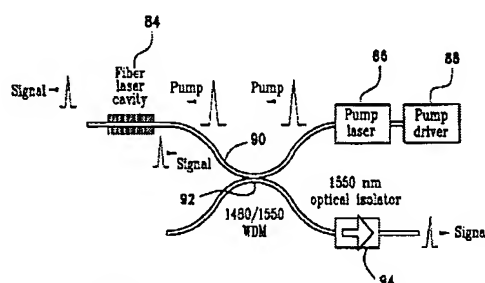


FIG. 6

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 12 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lading et al. in view of Ebersole et al. (U.S. Pat. No. 5,658,732 A). Lading et al. do not specifically teach the use of an immobilized chelating binding partner. Ebersole et al. do teach the incorporation of a chelating agent with an optical sensor for facilitating optical detection of analytes (see col. 18, lines 40 – 48; col. 19, line 45 – col. 20, line 33). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of a chelating agent, as taught by Ebersole et al., with the sensor of Lading et al. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a chelating agent, as taught by Ebersole et al., with the sensor of Lading et al. in order to facilitate the detection of analytes amenable to binding by chelation.

Response to Arguments

1. Applicant's arguments and amendments, filed 11/26/2004, with respect to the rejection of claim 5 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. This rejection has been withdrawn.
2. Regarding the rejection of claims 1 – 11, 13 – 25, 35 – 43 and 45 – 50 under 35 U.S.C. 102(e) as being anticipated by Lading et al. (U.S. Pat. No. 6,493,090 B1), applicant's arguments, filed 11/26/2004, have been fully considered, but they are not persuasive.

Regarding claims 1, 13 and 42, the applicant essentially argues that Lading et al. does not anticipate the claimed invention. However, as discussed above, Lading et al. do anticipate the

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apparatus structure claimed invention. Regarding claim 1, a duct is generally defined and understood by a person of ordinary skill in the art as an often enclosed passage or channel for conveying a substance, especially a liquid or gas. This definition is considered the plain meaning of the term “duct” with regards to the interpretation of the instant claim. The applicant is advised that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); *In re Barr*, 170 USPQ 330 (CCPA 1971). “The PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art.” See *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). “During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.” See *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). “The PTO broadly interprets claims during examination of a patent application since the applicant may ‘amend his claim to obtain protection commensurate with his actual contribution to the art.’”(quoting *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550 (CCPA 1969)). See *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). The applicant cannot read limitations set forth in the description into the claims for the purpose of avoiding the art. See *In re Sporck*, 155 USPQ 687 (CCPA 1967). Lading et al. teach an apparatus comprising a duct structure (e.g., microfluidics handling system 13), wherein the duct has a first wall and a substantially parallel gap formed by a first transparent wall and a second transparent wall (see col. 4, line 15 – col. 14, line 57; figures 1 – 6). Lading et al. teach that the microfluidics handling or duct system (13) can be monolithically integrated with the chip (18) (see col. 11, lines 45 – 51). Lading et al. do

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indicate that the substrate comprising the chip structure may comprise transparent or translucent materials, such as glass (see col. 7, lines 7, lines 49 – 55). In addition, Lading et al. do further teach the incorporation of an optical sensor (e.g., detector 10) within the apparatus (see col. 12, lines 23 – 25; figures 3 & 4). Thus, Lading et al. do teach the positively recited structure of the claimed apparatus. The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). Although the apparatus as taught by the prior art may not be what the applicant intends as their claimed invention, the claims still encompass the teachings of the prior art. Therefore, the claims still do not *exclude* the prior art apparatus structure.

Regarding claim 35, which pertains to a method of using the sensor, the applicant argues that Lading et al. do not anticipate the claimed methodology. However, Lading et al. do anticipate the claimed methodology. As discussed above, Lading et al. do teach the positively recited structure of the claimed apparatus. It is inherently anticipated that the refractive index of the structure forming the chamber would be different than the refractive index of an introduced sample fluid, since they are composed of different materials (see MPEP 2112). Lading et al. do teach the incorporation of an immobilized binding partner, such as an antibody or antigen, within a chamber of the apparatus (see col. 5, lines 9 – 30). Lading et al. do essentially teach the

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determination of a refractive index for the chamber containing a sample fluid (see col. 5, lines 25 – 43; col. 6, lines 6 – 67).

3. Regarding the rejection of claims 12 and 44 under 35 U.S.C. 103(a) as being unpatentable over Lading et al. in view of Ebersole et al. (U.S. Pat. No. 5,658,732 A), applicant's arguments, filed 11/26/2004, have been fully considered, but they are not persuasive. The applicant essentially argues that it would not have been obvious to combine the teachings of Ebersole et al. with the teachings of Lading et al. since these references are non-analogous art. In response to applicant's argument that Ebersole et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both disclosures of Ebersole et al. and Lading et al. relate to optical sensing techniques. Furthermore, the Courts have held that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." See *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990) (quoting *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986)). However, the "suggestion to modify the art to produce the claimed invention need not be expressly stated in one or all the references used to show obviousness." See *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1025, 226 USPQ 881, 886 (Fed. Cir. 1985). Rather, the test is whether the combined teachings of the prior art, taken as a whole, would have rendered the claimed invention obvious to one of ordinary skill in the art. See *In re Gorman*, 933 F.2d

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982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). The Courts have held that “[t]here are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 & 1458 (Fed. Cir. 1998) (see MPEP § 2143.01). Both of the optical detection techniques disclosed by Ebersole et al. and Lading et al. rely on binding phenomena imparting an index refraction change to facilitate detection (see Ebersole et al.: col.19, line 45 – col. 20, line 33; Lading et al.: col. 5, line 1 – col. 6, line 64). Ebersole et al. do teach the incorporation of a chelating agent for facilitating detection of analytes (see col. 18, lines 40 – 48). The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Therefore, a person of ordinary skill in the art would have recognized the suitability of utilizing a chelating agent to detect analytes, which are amenable to binding by chelating agents, in order to facilitate effective detection. Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, as evidenced by Ebersole et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of using a chelating agent as a binding partner in a detection apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a chelating agent, as taught by Ebersole et al., with the sensor of Lading et al. in order to facilitate the detection of analytes amenable to binding by chelation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Technology Center 1700